

REMARKS

I. Overview

Claims 1-22 and 24-32 are withdrawn from consideration. Claim 23 stands rejected by the Examiner. Claim 23 has been amended and withdrawn claims 25-32 have been amended. No new matter has been added.

II. Election/Restriction

Applicant acknowledge the Examiner's withdrawal of claims 1-22 and 24-32 as being drawn to non-elected subject matter. The Examiner states that newly submitted claims 25-32 are directed to an invention that is independent or distinct from the invention originally claimed as the new claims are directed to methods which lack unity of the invention since they claim patentably distinct methods from the elected method and it has been shown already on the record that the claims lack unity of invention since the composition is known in the art.

Applicant continues to traverse the Examiner's assertion that the claims lack unity of invention. Applicant has amended claims 25, 27-28 and 31-32 which Applicant respectfully requests the Examiner to reconsider, as the independent claims are amended to claim an additional "special technical feature" as required pursuant to 37 CFR §1.475 (regarding unity of invention before the International Searching Authority, the International Preliminary Examining Authority and during National Stage). Applicants amended claim feature of "modulating a physiological reaction or inducing an immune response in said human or animal" adds an addition technical relationship between the claims. Moreover, the modulating of a physiological reaction or induction of an immune

response in a human or animal defines a contribution set forth in claims 23 and 25-32 which makes over the prior art, as required pursuant to 37 CFR §1.475.

Moreover, Applicant has amended claim 23 and withdrawn independent claims 25 and 32 to include method steps rather than the composition of claim 1, to which the Examiner objects to under the unity of invention standard. Accordingly, Applicant respectfully requests the Examiner's final restriction of elected claim 23 separate from withdrawn claims 25-32, be reconsidered and withdrawn, in light of the claim amendments and Applicant's remarks regarding the § 103 rejection.

III. Claim Rejection Under 35 U.S.C. § 103

Claim 23 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Yamada *et al.* in view of DE 19927963. The Examiner states that Yamada *et al.* teaches orally administered active substances, including physiologically active substances, made into tablets containing deoxycholate. Further, the Examiner states that DE teaches ground coffee beans can be made into tablets for human oral application. The Examiner continues with the obviousness rejection by stating that known ingredients are *prima facie* obvious to combine. Applicant respectfully traverses the Examiner's obviousness rejection.

None of these references, neither alone or in combination, disclose the claimed invention nor provide any teaching to one skilled in the art to adopt the approach of the claimed invention. *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006); *In re Oetiker*, 977 F.2d 1443, 1445 (Fed. Cir. 1992). Accordingly, the Examiner has not met the burden of establishing a *prima facie* case of obviousness. *Id.* Further, the Examiner provided an

insufficient factual basis to support the legal conclusion of obviousness as required pursuant to *KSR Int'l Co. v. Teleflex Inc.* which requires more than mere conclusory statements. 127 S. Ct. 1727, 1734 (2007) (noting an obviousness rejection must include articulated reasoning with rational underpinning to support such a legal conclusion).

None of the references, alone or together teach the steps of: (1) orally administering to humans/animals a physiologically active agent to modulate physiological reactions or induce immune responses; (2) neutralizing the pH in the digestive system of said human or animal; (3) inhibiting digestive enzymes to prevent enzymatic digestion of said physiologically active agent; (4) increasing intestinal absorption of said physiologically active agent; nor (5) modulating a physiological reaction or inducing an immune response in a human or animal. Such steps are also incorporated into Applicant's amended independent claims 25 and 32, where the combination of references similarly fail to disclose such claim elements, in addition to the claim elements of: (1) admixing the physiologically active agent with a dry blended homogenous composition; (2) preventing degradation of a physiologically active agent; and (3) increasing oral bioavailability of the physiologically active agent.

Contrary to the Examiner's statement that Yamada *et al.* and DE disclose the elements of Applicant's claims, Yamada *et al.* merely discloses specific allosamidin compounds produced by bacteria to inhibit the growth of fungi, namely chitinase derived from *Candida albicans*. (*see, e.g.*, 5,413,991 col. 3, lines 15-35; col. 9, lines 29-36). In addition, as the Examiner points out, Yamada *et al.* contemplate the inclusion of various substances for the preparation of orally-formulated antifungal or insecticidal agents, including "dissolution aids such as sodium deoxycholate, etc." (*Id.* at col. 10, line 9).

However, the identification of a single component of Applicant's composition used in methods to enhance body uptake of a physiologically active agent or an antigen (claim 23); increase the oral bioavailability of a physiologically active agent in a human or animal to modulate a physiological reaction or induce immune response (claim 25); or prevent degradation of a physiologically active agent to a human or animal by the intestine of the same to modulate a physiological reaction or induce immune response (claim 32), does not render obvious the additional method steps of Applicant's claimed invention.

Further, the combination of the second cited reference, DE 19927963, with the disclosure of Yamada still does not arrive at the claimed invention set forth in claims 23 and 25-32. DE merely discloses the formulation of beverage tablets, containing ground coffee beans or tea leaves, that disintegrate and provide a more hygienic formulation than powers or granules (DE 19927963 pages 1-2). The reference teaches the use of ground coffee beans for tablet formulation for disintegration prior to human consumption. The reference does not disclose the oral use of tablets including the additional method steps of Applicant's amended claims (as set forth above), nor does it teach the use of ground coffee beans for the inhibition of digestive enzymes, neutralizing of a digestive system, nor preventing enzymatic digestion of the physiological agent administered with the composition. Here, DE merely discloses a new convenient form of coffee storage and handling and has nothing to providing the novel benefits of the composition administered in the various method steps of Applicant's claims.

Accordingly, the allowability of claims 23 and the amended withdrawn claims 25-32 over the obviousness rejection of record is confirmed by the Court's recent *KSR*

decision. As Applicant has clarified for the Examiner, the claimed invention is more than the predictable use of prior art elements, according to their established functions, as the references in combination fail to disclose the majority of Applicant's claim elements arriving far short of Applicant's claimed invention. Thus, allowability is wholly in accord with the recent *KSR* decision and office practice. The Applicant respectfully requests the Examiner reconsider and withdraw the rejection to place the claims in condition for allowance.

IV. Double Patenting

A. Claim 23 stands provisionally rejected on the ground of nonstatutory double patenting over claim 21 of co-pending Application No. 11/676,349. As the Examiner's rejection is provisional, Applicant will file a terminal disclaimer upon issuance of allowable subject matter.

B. Claim 23 stands provisionally rejected on the ground of nonstatutory double patenting over claims 1-6, 8, 10, 12-18, 20, 29-31 of co-pending Application No. 10/181,428. Again, as the Examiner's rejection is provisional, Applicant will file a terminal disclaimer upon issuance of allowable subject matter.

C. Claim 23 stands provisionally rejected on the ground of nonstatutory double patenting over claims 35-37 of co-pending Application No. 12/045,791. Again, as the Examiner's rejection is provisional, Applicant will file a terminal disclaimer upon issuance of allowable subject matter.

V. Conclusion

No fees or extensions of time are believed to be due in connection with this amendment; however, consider this a request for any extension inadvertently omitted, and charge any additional fees to Deposit Account No. 26-0084.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Heidi Nebel", is written over the printed name.

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